

US: 10/796,280
Atty. Docket: CL1510ORD**REMARKS****Status of the claims**

Claims 1-24 are pending. Claims 7-20, 23-24 were withdrawn as being drawn to non-elected subject matter.

By entry of this amendment, claims 2-5, 7-20, and 23-24 have been canceled without disclaimer or prejudice. Applicants reserve the right to pursue the subject matter encompassed in the canceled claims in subsequent continuation or divisional applications.

Claims 1 and 21 have been amended by this amendment. Claims 6 and 22 are as originally filed. New dependent claims 25-37 have been added. Thus, claims 1, 6, 21, 22, 25-37 are currently under examination.

No new matter has been added by these amendments.

Support for amended claims 1 and 21 can be found on pages 18, 116-118, Table 7, and the Sequence Listing.

Support for new claims 25, 26, 30, 31, 35 and 36 can be found in Table 2 and the Sequence Listing.

Support for new claim 27, 32, and 37 can be found on pages 16-18, and in Tables 5 and 7.

Support for new claim 28, 29, 33 and 34 can be found on pages 18, 116-118, Table 7 and the Sequence Listing.

This amendment adds, changes and/or deletes claims in the instant application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, are presented with an appropriate defined status identifiers. See 37 C.F.R. §1.121(c).

Title and Abstract of the Invention

A new title and abstract have been provided as requested by the Examiner.

Rejection under 35 USC §112, first paragraph, written description

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The claims stand rejected under 35 USC §112, first paragraph, for allegedly being not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner interpreted the claims to be broadly drawn to any SNP in SEQ ID NO: 19350. The Examiner stated that the specification teaches a single polymorphism at position 101, with respect to SEQ ID NO: 19350.

As amended, the claims now specify the exact identity of the SNP within SEQ ID NO: 19350.

Therefore, the rejection under 35 USC §112, first paragraph, for allegedly lack of adequate written description has been overcome. The Examiner is respectfully requested to withdraw the rejection.

Rejection under 35 USC §112, first paragraph, enablement

The claims stand rejected under 35 USC §112, first paragraph, for allegedly being not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner analyzed various factors in determining whether a disclosure meets the enablement requirement of 35 USC §112, first paragraph, quoting *in re Wands*, 8 USPQ2d 1400 (CAFC 1988).

For instance, the Examiner objected to the use of the term "individual", alleging that term could encompass human, dog, cat, etc. As amended, the claims under examination are directed to a human.

The Examiner also stated that the specification has not provided any guidance for an association of the SNP with any stenosis, which broadly encompasses coronary stenosis, spinal stenosis, aortic stenosis, pulmonary valve stenosis, etc.

It is well known that the Examiner bears the initial burden to make a *prima facie* case that the claims are enabled in the specification. As stated in the MPEP §2164.04,

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used

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in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Applicants have provided sufficient data analysis in the examples that the SNP at issue has been associated with coronary stenosis, as shown in the Examples section, and the tables of the instant application.

There can be no dispute that coronary stenosis is one form of stenosis. The Examiner has not provided any evidence whatsoever, showing that this particular SNP would NOT be useful in identifying risks of persons developing other forms of stenosis. No art was cited to suggest as such, and no logical reasoning has been provided to support such conclusion.

However, in the interest of expediting the prosecution of the instant application, applicants have amended the claims to recite coronary stenosis, without disclaimer or prejudice.

In addition, Applicants have performed additional post-filing genotyping experiments using the same two sample sets, confirming that the SNP hCV25930271, also known as rs 3798220 in the public database, is indeed associated with coronary stenosis (manuscript submitted, excerpt of the data is shown below).

SNP	Risk allele (frequency)	V0002 Sample		S0012 Sample	
		OR	P value	OR	P value
hCV25930271 (rs3798220)	G (0.02)	3.79	<0.001	2.25	0.010

Therefore, the rejection under 35 USC §112, first paragraph, for allegedly lack of enablement has been overcome. The Examiner is respectfully requested to withdraw the rejection.

In conclusion, in light of the amendments and remarks above, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly requested.

The Examiner is invited to contact the undersigned via telephone if a phone interview would expedite the prosecution of the instant patent application.

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Respectfully submitted,

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